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DEC 1 8 2001

K011907

Summary of Safety and Effectiveness

510(k) Premarket Notification for the
***Snuggle Warm*® 4000 Convective Warming System**

US FDA, Division of General, Restorative and Neurological Devices (DGRND)
Branch: General Surgery Devices

The following information is provided in accordance with 21 CFR 807.92(a):

1. Sponsor name and address:

   SIMS® LEVEL 1®, Inc.
   160 Weymouth Street,
   Rockland, MA. 02370

2. Sponsor telephone number: 781-878-8011, Ext. 730

3. Contact Person: Gabriel J. Muraca, Jr. – Manager Regulatory Affairs

4. Date summary was prepared: June 6, 2001

5. Device Name: ***Snuggle Warm*® 4000 Convective Warming System**

6. Common Name: an external convective warming system used to warm the patient during and after surgical procedures.

7. The legally marketed predicate device currently in commercial distribution is the **Temp Marq™/ *Snuggle Warm*** Convective Warming System, described in premarket notification K904690 and cleared for market on February 1, 1991.

8. Description of device:

The ***Snuggle Warm*** consists of a disposable single use warming blanket that is placed in contact with the patient and a warming unit with a hose end temperature control connected to the blanket. The warming unit generates warm air that is distributed throughout the warming blanket to warm the patient during and after surgical procedures. It is intended for use by appropriately trained healthcare professionals in clinical environments.

9. Indications for use:

The ***Snuggle Warm*** Convective Warming System is intended for thermal regulating a patient's temperature to prevent hypothermia by a warm air heated blanket system to reduce cold discomfort during and after surgical procedures. It is intended for use by appropriately trained healthcare professionals in clinical environments.

10. Technological characteristics:

There are no significant changes in technological characteristics or intended use that impact the safety or effectiveness of these warming devices. As described in this submission, **Level 1** has initiated modifications to improve the performance of the ***Snuggle Warm* 4000** without affecting the safety or effectiveness of the Convective Warming System. The ***Snuggle Warm*** Convective Warming Systems are manufactured and certified in compliance with applicable International and US standards.

Gabriel J. Muraca, Jr.

Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
SIMS® LEVEL 1®, Inc.

June 6, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2001

Mr. Gabriel J. Muraca, Jr.
Manager, Regulatory Affairs
SIMS Level 1, Inc.
160 Weymouth Street
Rockland, MA 02370

Re: K011907
Trade Name: Snuggle Warm® 4000 Convective Warming System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulation System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: September 28, 2001
Received: October 2, 2001

Dear Mr. Muraca:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K011907

Device Name: ***Snuggle Warm*® 4000 Convective Warming System**

Indications for Use:

The ***Snuggle Warm 4000*** Convective Warming System is intended for thermal regulating a patient's temperature to prevent hypothermia by a warm air heated blanket system to reduce cold discomfort during and after surgical procedures. It is intended for use by appropriately trained healthcare professionals in clinical environments.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011907

Prescription Use ✓ OR Over-the-Counter Use
(Per 21 CFR 801.109)